May 22, 2003

Natalie Rutherford
Global Regulatory Manager
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Dear Ms. Rutherford:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Methyl 3,3-dimethyl-4-pentenoate posted on the ChemRTK HPV Challenge Program Web site on January 28, 2003. I commend FMC Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that FMC Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: A. Abramson
W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Methyl 3,3-Dimethyl-4-pentenoate

Summary of EPA Comments

The sponsor, FMC Corporation, submitted a test plan and robust summaries to EPA for Methyl 3,3-Dimethyl-4-pentenoate (CAS No. 63721-05-1) dated December 30, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 28, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. EPA agrees with the test plan for these endpoints.

2. Health Effects. EPA believes that information provided by the submitter is not sufficient to meet the criteria for claiming methyl 3,3-dimethyl-4-pentenoate as a closed-system intermediate. EPA agrees with the submitter's plan to conduct testing for chromosomal aberrations and developmental toxicity.

3. Ecological Effects. The submitted data for acute fish toxicity are inadequate. Testing is needed for this endpoint. EPA agrees that testing is needed for aquatic invertebrates and algae.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Methyl 3,3-dimethyl-4-pentenoate Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

EPA agrees with the test plan for these endpoints.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA agrees with the test plan for these endpoints. However, the submitter needs to provide revised estimations based on the measured physicochemical properties.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for the acute toxicity endpoint and gene mutations for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct testing for chromosomal aberrations and developmental toxicity following OECD TG 473 (*in vitro* mammalian chromosomal aberration test) and 421 (reproduction/developmental toxicity screening test), respectively.

Repeated-Dose and Reproductive Toxicity. No data were submitted for these endpoints and no testing is proposed, based on the submitter's assertion that methyl 3,3-dimethyl-4-pentenoate is a closed-system intermediate.

The Guidance for Testing Closed System Intermediates for the Challenge Program http://www.epa.gov/chemrtk/guidocs.htm allows for a reduced testing protocol provided certain criteria are met. The information required to judge a "closed-system intermediate" claim must address the following:

I. Site information
    A. Number of sites.
    B. Basis for "closed process" conclusion at each site.
        1) Process description.
        2) Monitoring data showing no detection.
        3) In the absence of monitoring data, the basis for believing that releases do not occur.
    C. Data on "presence in distributed products."
II. Information on transport (mode, volume, controls, etc)
III. A data search showing that the chemical is not present in other end products.

Closed-System Intermediate Review.

EPA believes that information provided by the submitter is not sufficient to meet the criteria for claiming methyl 3,3-dimethyl-4-pentenoate as a closed-system intermediate because information on manufacture of the chemical is not provided in the test plan and information on transport of the chemical is inadequate.

I. Site information

A. Number of sites.

The test plan does not discuss the number of sites manufacturing or processing this chemical. However the Inventory Updates for 1990, 1994, and 1998 list only the site identified in the test plan as reporting for this chemical.

B. Basis for "closed process" conclusion at each site.
1) Process description.

No information is provided in the test plan on the manufacture of the chemical.

Although the flow diagram includes an illustration of a tank truck delivering the chemical, the test plan states that the subject chemical is not transported on the site or off site.

Methyl 3,3-dimethyl-4-pentenoate is unloaded from tank trucks using nitrogen to displace the liquid chemical. The subject chemical is stored in a closed tank which is vented to a water scrubber and carbon adsorption system. The chemical is pumped through closed piping to a reactor where the intermediate chemical reacts with carbon tetrachloride to produce another chemical substance. The reactor is vented through two condensers to parallel carbon adsorbers which are open to the atmosphere.

2) Monitoring data showing no detection.

Wastewater from the facility which presumably includes water from the scrubber for the storage tank is monitored for the subject chemical. In 2002, the average concentration of the chemical in the wastewater stream was 1.55 ppm.

Workplace air monitoring was conducted at 20 sampling locations in 1987. The chemical was detected in two air samples at levels of 1.0 ppm and 0.8 ppm. The chemical was not detected in samples from other locations. The limit of detection at the time of sampling was 0.5 ppm.

C. Data on “presence in distributed products.”

The test plan states that the chemical is not present in any finished goods products manufactured from the subject chemical intermediate. No basis is provided for this statement.

II. Information on transport (mode, volume, controls, etc)

The test plan states that the subject chemical is not transported on the site or off the site. However, the flow diagram shows delivery by tank truck and preceding statements indicate that the subject chemical is unloaded from tank trucks using low pressure nitrogen displacement.

III. A data search showing that the chemical is not present in other end products.

Results from a search of the Chemical Abstracts On-Line Database indicate that the chemical is not present in any end products.

The chemical is not included in any Confidential Statement of Formula for the technical materials which use chemicals produced from the chemical at the identified site.

Ecological Effects (fish, invertebrates, and algae)

The submitted data for acute fish toxicity are inadequate. The Henry’s law constant and chemical structure suggest that this chemical is volatile. The submitted fish study was conducted using nominal concentrations in which the chemical’s volatility was not accounted for during the test. The submitter needs to provide a rationale as to why the submitted data using nominal concentrations are adequate taking into account the results from the proposed physicochemical testing. Any testing conducted needs to use a closed system with no head space and mean measured concentrations. EPA agrees that testing is needed for aquatic invertebrates and algae with measured concentrations.

Specific Comments on the Robust Summaries

Health Effects.

Genetic Toxicity (Gene Mutations). The omitted information in the robust summary for the bacterial mutation test included the type of positive controls used and the criteria for positive results.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.